Chapter 2.3.13. - Bovine Spongiform Encephalopathy

Article 2.3.13.1

Current text as proposed:

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE status of the cattle population of the exporting country or zone/compartment:

a) *milk* and *milk products*;

b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

c) hides and skins (excluding hides and skins from the head);

d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);

e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

f) dicalcium phosphate (with no trace of protein or fat).

2) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE status of the cattle population of the exporting country or zone/compartment:

   a) cattle;

   b) *fresh meat* and *meat products*;

   c) gelatin and collagen prepared from bones or from hides and skins from the head;

   d) tallow and tallow derivatives, other than protein-free tallow as defined above;

   e) dicalcium phosphate, other than dicalcium phosphate with no trace of protein or fat.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Suggested text:

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE status of the cattle population of the exporting country or zone/compartment:

a) *milk* and *milk products*;

b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

c) hides and skins ~~(excluding hides and skins from the head);~~

d) gelatin and collagen prepared exclusively from hides and skins ~~(excluding hides and skins from the head);~~

e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

f) dicalcium phosphate (with no trace of protein or fat).

2) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE status of the cattle population of the exporting country or zone/compartment:

a) cattle;

b) *fresh meat* and *meat products*;

c) gelatin and collagen prepared from bones ~~or from hides and skins from the head;~~

d) tallow and tallow derivatives, other than protein-free tallow as defined above;

e) dicalcium phosphate, other than dicalcium phosphate with no trace of protein or fat.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Discussion/rationale: The United States requests that the text in this Article (items 1.c, 1.d, and 2.c) revert back to the way it was written in the 2003 version of the *Code*.

Item 1.c and 1.d exclude "hides and skins from the head" and "gelatine…from hides and skins from the head" as no risk products regardless of the BSE status of the cattle population of the exporting country or zone. Regulatory and scientific authorities around the world consider bovine hides and skins to be a safe raw material for the production of gelatine, provided there is no contamination by specified risk materials. For example, the U.S. FDA in its Guidance for Industry The Sourcing and Processing of Gelatine to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use (September, 1997) stipulates:

> 5. At this time, there does not appear to be a basis for objection to the use of gelatin produced from bovine hides, from any source country, in FDA-regulated products for oral consumption and cosmetic use by humans **if processors ensure that the bovine hides have not been contaminated** with brain, spinal cord, or ocular tissues of cattle residing in, or originating from, BSE countries and if they exclude hides from cattle that have signs of neurological disease.

Also the EU's Scientific Steering Committee in its Updated Opinion on the Safety of Gelatine (January 21, 2000) states on the topic of sourcing raw material:

> For countries where the presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a region or country is highly unlikely (GBRI) sourcing of raw materials from any animal is in principle safe with regard to BSE risks….
>
> For other countries, the safest sourcing of the material would in principle be (1) from animals that passed (for hides) the ante mortem inspection as fit for human consumption… and (2) if the risk of cross contamination with specified risk materials or potentially contaminated materials is **minimal**.

Note: in the event that the Code Commission is unable to reach a decision to revert back to the language that existed in the 2003 version of the Code, then, in the interim, the proposed text, under Article 2.3.13.19 needs to be clarified. We welcome the change the Code Commission has made giving recognition to the fact that the BSE risk associated with "hides and skins from the head" that are sourced from BSE free, provisionally free, or minimal risk countries/zones are of minimal risk concern. However, we also believe that such "hides and skins from the head" are also of minimal concern when sourced from moderate BSE risk countries/zones when appropriate processing steps are followed prior to their use. Hence, our recommendations to Article 2.3.13.19 follow below:

Article 2.3.13.19

Current text as proposed text:

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones or from hides and skins from the head and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the ~~bones~~ *commodities* came from:

1) a BSE free or provisionally free country or zone/compartment, or from a country or zone/compartment with a minimal BSE risk; or

2) a country or zone/compartment with a moderate BSE risk; and

   a) skulls and vertebrae (excluding tail vertebrae, and from hides and skins from the head) have been excluded;

   b) the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Suggested text:

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones or from hides and skins from the head and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the ~~bones~~ *commodities* came from:

1) a BSE free or provisionally free country or zone/compartment, or from a country or zone/compartment with a minimal BSE risk; or

2) a country or zone/compartment with a moderate BSE risk; and

   a) skulls and vertebrae (~~excluding~~ except tail vertebrae), ~~and from hides and skins from the head)~~ have been excluded~~;~~

   b) in the case of bones: the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

iv) filtration,

v) sterilisation at ≥138°C for a minimum of 4 seconds,

or to an equivalent process in terms of infectivity reduction.

c) in the case of hides and skins from the head:

i) the hides and skins from the head have been obtained from animals that have not been stunned using a method that penetrates the skull; or

ii) the hides and skins from the head have been subjected to a process which includes the following steps:

1) treatment with acid or alkali;

2) one or more successive rinses;

3) extraction by heating one or more times in succession

4) purification by means of filtration and sterilization

Rationale:

Hides and skins from the head are not part of the skulls and vertebrae and unlike tail vertebrae, should not be included within the parenthesis. Additionally, the type of potential infectivity of hides and skins from the head is different from that of skulls and vertebrae and should be treated separately.

The concern over hides and skins from the head, as opposed to those from other parts of the body, has arisen due to the potential cross contamination of the hide by brain matter during penetrative stunning methods, particularly where this procedure is used more than once. If such a stunning method were not used, e.g., where electrical stunning is used or non-penetrative stunning with a mushroom bolt is used, no such risk exists. Where there is no risk of contamination, the hides and skins from the head should be derogated from the additional requirements and treated as other hides and skins.

Should a penetrative stunning method be employed and a risk of contamination of the surface hair exists, then any further required processing need only address this potential surface contamination. Normal soaking of the hides in alkali for hair removal and subsequent washing is sufficient to remove any contamination.

Article 2.3.13.20

Current proposed text:

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a BSE free or provisionally free country or zone/compartment, or

2) a country or zone/compartment with a minimal BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.18., or

3) a country or zone/compartment with a moderate BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.18.

Suggested text:

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a BSE free or provisionally free country or zone/compartment, or

2) a country or zone/compartment with a minimal BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem inspection and post-mortem inspection (i.e., inspection after slaughter that ensures that specified risk materials have been removed and removal was done in a manner so as to avoid contamination) for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.18., or

3) a country or zone/compartment with a moderate BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem inspection and post-mortem inspection (i.e., inspection after slaughter that ensures that specified risk materials have been removed and removal was done in a manner so as to avoid contamination) for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.18.

Rationale:

In this article, "post-mortem" inspection needed clarification. The intent in using the *post-mortem* inspection language is to address the fact that countries must have also inspected the carcasses after slaughter and ensure that certain high risk tissues (i.e. small intestine, spinal cord, etc) have been removed and that they were removed in a manner so as to avoid contamination.

Article 2.3.13.2

Current proposed text:

Article 2.3.13.2.

The BSE risk status of the cattle population of a country or zone/compartment can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:

a) Release assessment

Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced into the cattle population from a pre-existing TSE in the indigenous ruminant population or via the ~~importation of the~~ following commodities potentially contaminated with a TSE agent:

i)a) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

i)b) imported *meat-and-bone meal* or *greaves*;

ii) imported live animals;

iii) imported animal feed and feed ingredients;

iv) imported products of ruminant ~~animal~~ origin for human consumption, which may have contained tissues listed in Article 2.3.13.18 and may have been fed to cattle;

v) imported products of ruminant origin for *in vivo* use in cattle.

b) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle ~~susceptible animal species~~, through a consideration of the following:

i)a) ~~epidemiological situation concerning all~~ the presence or absence of animal TSE agents in the country or zone/compartment and, if present, their prevalence based on the outcomes of surveillance;

i)b) prevalence of infection of animals with TSE agents in the country or zone/compartment, including the surveillance and other epidemiological investigations on which the determination is based;

ii) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

iii) the ~~origin and~~ use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iv) ~~implementation and enforcement of feed bans,~~ the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 3.8.4.2 and 3.8.4.3 ~~of neurological disease in adult cattle as well as fallen stock~~;

3) compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;

5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

Suggested changes

Article 2.3.13.2.

The BSE risk status of the cattle population of a country or zone/compartment can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:

a) Release assessment

Release assessment consists of assessing the likelihood that ~~a transmissible spongiform encephalopathy (TSE)~~ **the BSE** agent has been introduced ~~into the cattle population from a pre-existing TSE in the indigenous ruminant population or~~ via the importation of the following commodities potentially contaminated with a TSE agent:

i)a) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

i)b) imported *meat-and-bone meal* or *greaves*;

ii) imported live animals;

iii) imported animal feed and feed ingredients;

iv) imported products of ruminant ~~animal~~ origin for human consumption, which may have contained tissues listed in Article 2.3.13.18 and may have been fed to cattle;

v) imported products of ruminant origin for *in vivo* use in cattle.

b) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to ~~cattle~~ susceptible animal species, through a consideration of the following:

i)~~a)~~ epidemiological situation concerning ~~all~~ the presence or absence of animal TSE agents in the country or zone/compartment and, if present, their prevalence based on the outcomes of surveillance;

~~i)b) prevalence of infection of animals with TSE agents in the country or zone/compartment, including the surveillance and other epidemiological investigations on which the determination is based;~~

ii) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

iii) the ~~origin and~~ use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iv) ~~implementation and enforcement of feed bans,~~ the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 3.8.4.2 and 3.8.4.3 ~~of neurological disease in adult cattle as well as fallen stock~~;

3) compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;

5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

Rationale:

The incorporation of general language about TSE's in indigenous populations, and the broadening of references to all TSE agents causes concern. This could be interpreted in a misleading manner. For example, the new language in 1) (a) could be interpreted to mean that the presence of chronic wasting disease in the wild cervidae population presents a significant risk of introducing a TSE – or more specifically, BSE – into cattle. Yet, research to date shows no risk of naturally occurring transmission of CWD into cattle. Similarly, this could be interpreted to mean that any country that has scrapie in its' sheep population automatically has a risk of BSE in cattle. While we do not dispute the possibility that BSE originated from a strain of scrapie, this is far from definitive, nor can it be assumed that all TSEs in indigenous ruminant populations present equivalent risks of cross-species transmissions.

The opposite assumptions, however, should be incorporated into this chapter. If BSE has been identified in the cattle population, then the possibilities of BSE exposure in small ruminant populations must be considered and addressed.

We recommend that the language directly under 1) a) [Release assessment] remain as it is in the current chapter, with one clarification. The language throughout this Article should be consistent in references to either BSE in cattle, or a TSE in cattle. The language in the exposure assessment paragraphs refers to BSE in cattle. We believe this same specific identification of the agent of concern should be referenced in the release assessment – i.e., "Release assessment consists of assessing the likelihood that the BSE agent has been introduced via the importation of the following commodities ….."

The language under1) (b) [Exposure assessment] should also remain as it is in the current chapter. This specifically references the BSE agent, and it also incorporates consideration of exposure of other susceptible animal species such as sheep and goats.

The sub-paragraphs of 1) (b), i)a) and i)b) appear to be redundant. We suggest that only the following statement be included:

(i) epidemiological situation concerning the presence or absence of animal TSE agents in the country or zone/compartment and, if present, their prevalence based on the outcomes of surveillance;